IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA LTD. And VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE S.A.S.,	)	
Plaintiffs,	)	C.A. No. 18-390-MN [redacted]
v.	)	
LUPIN ATLANTIS HOLDINGS SA, LUPIN PHARMACEUTICALS, INC., and TEVA PHARMACEUTICALS USA, INC.	)	
Defendants.	)	

PLAINTIFFS' BRIEF IN SUPPORT OF THEIR MOTION TO PRECLUDE PORTIONS OF THE EXPERT TESTIMONY OF WALTER G. CHAMBLISS, PH.D.

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Raymond N. Nimrod (admitted *pro hac vice*)
Steven C. Cherny (admitted *pro hac vice*)
Matthew A. Traupman (admitted *pro hac vice*)
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
FARNAN LLP
919 N. Market Str., 12th Floor
Wilmington, DE 19801
Tel: (302) 777-0300
Fax: (302) 777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Lauren N. Martin (admitted *pro hac vice*)
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
111 Hungtington Ave, Suite 520
Boston, MA 02199
(617) 712-7100

Nancy Zhang (admitted *pro hac vice*)
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
50 California St #22
San Francisco, CA 94111
(415) 875-6600

Attorneys for Plaintiffs Vifor Fresenius Medical Care Renal Pharma, Ltd. and Vifor Fresenius Medical Care Renal Pharma France S.A.S.

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Pursuant to Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), Plaintiffs Vifor Fresenius Medical Care Renal Pharma Ltd. and Plaintiffs Vifor Fresenius Medical Care Renal Pharma France S.A.S. (collectively "Plaintiffs" or "VFMCRP") respectfully move to preclude portions of the expert opinions of Dr. Walter Chambliss, Ph.D.

I. INTRODUCTION

Portions of Dr. Chambliss' proffered testimony should be precluded for two reasons. First, Dr. Chambliss failed to apply the correct legal standard when conducting his analysis under the reverse doctrine of equivalents and when determining if one prior art reference incorporates by reference another reference. Second, when offering opinions on inequitable conduct, Dr. Chambliss offers opinions on Dr. Philipp's state of mind, including what he knew and was aware of when he submitted a declaration to the PTO in 2015.

Although Plaintiffs are cognizant that the "the *Daubert* gatekeeping obligation is less pressing in connection with a bench trial," *AngioScore, Inc. v. TriReme Med., Inc.*, 87 F. Supp. 3d 986, 1016 (N.D. Cal. 2015), the challenged portions of Dr. Chambliss' testimony should be precluded because they will not assist the Court as the trier of fact. To the contrary, allowing an expert to offer opinions based on incorrect legal standards will introduce unreliable opinions into the trial record and needlessly prolong the trial. Accordingly, Courts in this District consistently preclude expert testimony that is not premised upon a proper understanding of the law. *See infra*, pp. 2-3. Likewise, Courts have recognized that it is not helpful to permit expert testimony regarding another person's state of mind. *See infra*, p. 9. This type of testimony is inherently speculative and unreliable—Dr. Chambliss has no possible basis to testify about what Dr. Philipp knew or had in mind at any point in time, in particular when he submitted his declaration to the

PTO in 2015. Accordingly, Plaintiffs respectfully request that the Court prohibit Dr. Chambliss from offering opinions on these topics.

II. LEGAL STANDARDS

"Pursuant to Rule 702, in order to be admissible, expert testimony must 'assist the trier of fact to understand the evidence or to determine a fact in issue.'" *B. Braun Melsungen AG v. Terumo Medical Corp.*, 749 F. Supp. 2d 210, 222 (D. Del. 2010). "Rule 702 embodies three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit." *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3rd Cir. 2000); *see also B. Braun*, 749 F. Supp. 2d at 222. "Qualification refers to the requirement that the witness possess specialized expertise." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3rd Cir. 2003). "Reliability" requires that expert testimony "be based on the methods and procedures of science rather than on subjective belief or unsupported speculation." *Id.* (internal quotations omitted). The "burden is placed on the party offering expert testimony to show that it meets all of the standards for admissibility." *B. Braun*, 749 F. Supp. 2d at 222.

III. ARGUMENT

A. Dr. Chambliss' Opinions That Are Based On Incorrect Legal Standards Should Be Excluded

Courts in this district and elsewhere have consistently excluded expert opinions that are based upon an incorrect understanding of the law. "When an expert witness's 'understanding of the law is incorrect,' it can 'render[ ] his opinion unreliable.'" *Liqwd, Inc, v. L'Oreal USA*, 2019 WL 8014103, at *5 (D. Del. June 25, 2019) (quoting *Intellectual Ventures I LLC v. Xilinx, Inc.*, No. CV 10-1065-LPS, 2014 WL 1814384, at *3 (D. Del. Apr. 14, 2014)); *see also Sprint Commc'ns Co. L.P. v. Cox Commc'ns Inc.*, 302 F. Supp. 3d 597, 624 (D. Del. Nov. 9, 2017) (excluding expert testimony because "the court has no confidence that [the expert] 'has reliably

applied the principles and methods to the facts of the case'" based in part on the fact that the expert "improperly applie[d] legal principles, such as those relating to claim construction, prosecution history estoppel, and double patenting"); *Cave v. Saxon Mortgage Services, Inc.*, 2015 WL 6153754, at *9 (E.D. Pa. Oct. 19, 2015) (excluding as "unreliable and inadmissible under *Daubert*" expert opinions that are "contrary to [the Court's] prior rulings"); *GlaxoSmithKline LLC v. Glenmark Pharms. Inc.*, 2017 WL 8948975, at *7 n.6 (D. Del. May 30, 2017) (recommending exclusion of expert testimony based on "faulty application of the law").

Here, Dr. Chambliss applied the wrong legal standard in two discrete topics—the reverse doctrine of equivalents and incorporation by reference. His opinions on these topics should be excluded.

1. Dr. Chambliss Applied The Wrong Legal Standard For The Reverse Doctrine Of Equivalents

Dr. Chambliss opines that Teva does not infringe any of the asserted claims based on the reverse doctrine of equivalents. "The reverse doctrine of equivalents is 'an equitable doctrine designed to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention.' . . . Its application is limited to circumstances 'where a device is so far changed in ***principle*** from a patented article that it performs the same or similar function in a ***substantially different way***, but nevertheless falls within the literal words of the claim.'"[1] *Kraft Foods Grp. Brands LLC v. TC Heartland, LLC*, 232 F. Supp. 3d 632, 634 (D. Del. 2017) (emphasis in original) (quoting *Roche Palo Alto LLC v. Apotex, Inc.*, 531 F.3d 1372, 1377 (Fed. Cir. 2008)).

[1] As noted by the Federal Circuit, "[b]ecause the reverse doctrine of equivalents requires a fundamental change in the basic principle by which the device operates, the doctrine is rarely invoked and virtually never sustained" *DePuy*, 567 F.3d at 1338. Indeed, the Federal Circuit has never affirmed a finding of non-infringement under the reverse doctrine of equivalents. *Id.* (citing *Roche*, 531 F.3d at 1378 ("[T]his court has never affirmed a finding of non-infringement under the reverse doctrine of equivalents.")).

The burden of proof for the reverse doctrine of equivalents is on the accused infringer, *SRI Int'l v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1123-24 (Fed. Cir. 1985), and significantly for this motion, "[t]he reverse doctrine of equivalents, like the doctrine of equivalents, is applied to individual limitations of a claim." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1338 (Fed. Cir. 2009); *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997) ("[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole."). In addition, "[t]he 'principle' or 'equitable scope of the claims' of the patented invention is determined in light of the specification, prosecution history, and the prior art." *Roche*, 531 F.3d at 1378.

Dr. Chambliss' opinions on reverse doctrine of equivalents misapply the law in two respects. First, Dr. Chambliss' expert report does not make any mention of the requirement that the reverse doctrine of equivalents is applied to individual claim limitations. The entirety of Dr. Chambliss' understanding of the law regarding the reverse doctrine of equivalents is found in Paragraphs 17 and 18 of Ex. A, Rebuttal Expert Report of Walter G. Chambliss, Ph.D. ("Rebuttal Report"), neither of which discuss applying the reverse doctrine of equivalents to individual claim limitations:

[redacted]

Ex. A, Rebuttal Report at ¶¶ 17, 18.

Dr. Chambliss' opinions regarding the reverse doctrine of equivalents do not include any application of the doctrine to any individual claim limitations. Dr. Chambliss' analysis under the reverse doctrine of equivalents is found in Paragraphs 70-80 of his Rebuttal Report (Ex. A). None of those paragraphs even mention a particular limitation of the asserted claims, let alone analyze a specific limitation to explain how the reverse doctrine of equivalents should be applied to that individual limitation. Instead, Dr. Chambliss simply attempts to identify the "principle" of the overall invention and argues that Teva's ANDA Product does not employ this overall "principle" of the invention without any discussion of the claim language.

Dr. Chambliss' analysis is flawed in a second respect—he failed to apply the correct legal standard when determining the alleged "principle" of the invention. Although he correctly states in his "Understanding of the Law" section that the "principle" of the patented invention is determined in light of the ***intrinsic evidence only***—the specification, prosecution history and prior art—Dr. Chambliss deviated from this standard when conducting his analysis. As he explicitly states in his report, Dr. Chambliss considered internal Vifor documents and inventor testimony when determining the "principle" of the invention: [redacted] Ex. A, Rebuttal Report at ¶ 72. Dr. Chambliss' reliance on internal Vifor documents and inventor testimony to determine the "principle" of the invention has no basis in the law.

Thus, Dr. Chambliss' analysis is contrary to the legal standards set forth by the Federal Circuit in two respects: 1) his failure to tie his opinions under the reverse doctrine of equivalents to individual claim limitations and 2) his consideration of internal Vifor documents and inventor testimony when determining the alleged "principle" of the invention. Accordingly, Dr. Chambliss' opinions on the reverse doctrine of equivalents are unreliable and unhelpful to the Court for two independent reasons; they should be excluded. *DePuy*, 567 F.3d at 1338; *Roche*, 531 F.3d at 1378.

2. Dr. Chambliss Applied The Wrong Legal Standard For Incorporation By Reference

Dr. Chambliss opines that the asserted claims are anticipated by a 1999 publication that he calls "Hergesell 1." In order to support his anticipation opinions, Dr. Chambliss alleges that Hergesell 1 incorporates by reference a second prior art reference, the '442 patent,[2] thereby allowing him to consider the disclosures of both prior art references in his anticipation analysis. Dr. Chambliss' understanding of the legal standard for incorporation by reference was set forth in his Opening Report:

Ex. B, Opening Expert Report of Walter G. Chambliss, Ph.D. ("Opening Report") at ¶ 22; Ex. C, Deposition of Walter G. Chambliss (February 7, 2020) ("Chambliss Dep.") at 62:10-21.

[2] Hergesell 1 cites to the German counterpart of the '442 patent. Because that document is in German, the parties have been using the '442 patent in their invalidity analysis.

Deducing what the host document aims to incorporate is not the correct legal standard for determining whether and to what extent there has been an incorporation by reference.

"To incorporate material by reference, the host document must identify ***with detailed particularity*** what ***specific material*** it incorporates and ***clearly indicate where that material is found*** in the various documents." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (emphasis added); *see also Paice LLC v. Ford Motor Co.*, 811 F.3d 894, 906 (Fed Cir. 2018); *see also Telcordia Techs., Inc. v. Lucent Techs., Inc.*, 514 F. Supp. 2d 598, 610-11 (D. Del. 2007), *aff'd sub nom. Telcordia Techs., Inc. v. Cisco Sys., Inc.*, 612 F.3d 1365 (Fed. Cir. 2010) (citing *Advanced Display*, 212 F.3d at 1282). In *Advanced Display*, the Federal Circuit further explained that incorporation by reference is a question of law and that "the standard of one reasonably skilled in the art should be used to determine whether the host document describes the material to be incorporated by reference with sufficient particularity." *Advanced Display*, 212 F.3d at 1283. Federal Circuit precedent does not permit incorporation by reference based on "what a reasonably skilled artisan would deduce that the host document aims to incorporate," as Dr. Chambliss alleges.

Dr. Chambliss made no attempt to apply the correct legal standard in conducting his invalidity analysis. He did not [redacted] Nor did he explain how Hergesell 1 clearly indicates where the incorporated material can be found in the '442 patent. *Id.* To the contrary, Dr. Chambliss [redacted]

Instead, the entirety of Dr. Chambliss' incorporation opinions are based on his own subjective standard of what a skilled person would deduce is incorporated into Hergesell 1. Ex. C, Chambliss Dep. at 61:25-62:21, 64:1-65:13, 68:14-69:24, 72:18-73:2, 73:9-75:22, 81:13-82:2. Dr. Chambliss' opinions are completely divorced from the rigorous standard for incorporation set forth by the Federal Circuit, and they are unreliable and unhelpful to any of the issues in this case. They should therefore be excluded.

B. Dr. Chambliss' Testimony Regarding Dr. Philipp's "Awareness" Of Certain Facts Should be Excluded as Unreliable

Defendants allege that Dr. Erik Philipp, one of the co-inventors of the '251 patent committed inequitable conduct when he submitted a declaration to the PTO stating that he was "unaware [sic] ferric oxyhydroxide dextrans have ever been suggested, used or registered to be used as a phosphate-adsorbing drug." *See, e.g.*, D.I. 135 at ¶¶ 29, 48, 71, 79, 80, 81; D.I. 136 at ¶¶ 3, 25, 44, 66, 69, 74-76. To support these allegations, Dr. Chambliss repeatedly offers opinions about what information Dr. Philipp was allegedly aware of or knew of:

[redacted]

Courts routinely exclude expert testimony relating to another individual's state of mind. "Expert witnesses are not 'permitted to testify ... regarding [the defendant's] intent, motive, or state of mind, or evidence by which such state of mind may be inferred.'" *AstraZeneca LP v. Tap Pharmaceutical Products, Inc.*, 444 F. Supp. 2d 278, 293 (D. Del. 2006) (quoting *Oxford Gene Tech. Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 443 (D. Del. 2004)); *see also ART+COM Innovationpool GmbH v. Google Inc.*, 155 F. Supp. 3d 489, 510 (D. Del. 2016) (holding that Defendant's expert "is not, however, an expert on [the inventor's] state of mind, and therefore cannot opine on whether [the inventor] was lying or mistaken when he authored his declaration" to the PTO that was alleged to constitute inequitable conduct); *In re Rosuvastatin Calcium Patent Litigation*, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009); *Liqwd*, 2019 WL 8014103,

at *5 ("The Court will not permit Mr. Schultz to testify as to the state of mind of multiple witnesses and parties.").

Dr. Chambliss' opinions in this case highlight why expert testimony regarding a person's state of mind are not admissible. Dr. Chambliss has [redacted] Dr. Chambliss' opinions regarding Dr. Philipp's "awareness" of certain facts are thus entirely speculative and unreliable. They should therefore be excluded.

IV. CONCLUSION

Plaintiffs request that the Court exclude the portions of Dr. Chambliss' opinions that: 1) apply the incorrect legal standard on the reverse doctrine of equivalents and incorporation by reference and 2) relate to Dr. Philipp's alleged awareness or knowledge.

Dated: February 28, 2020

Respectfully submitted,

FARNAN LLP

/s/ Michael J. Farnan

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 N. Market Str., 12th Floor
Wilmington, DE 19801
Tel: (302) 777-0300
Fax: (302) 777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Raymond N. Nimrod (admitted *pro hac vice*)
Steven C. Cherny (admitted *pro hac vice*)
Matthew A. Traupman (admitted *pro hac vice*)
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

Lauren N. Martin (admitted *pro hac vice*)
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
111 Hungtington Ave, Suite 520
Boston, MA 02199
(617) 712-7100

Nancy Zhang (admitted *pro hac vice*)
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
50 California St #22
San Francisco, CA 94111
(415) 875-6600

Attorneys for Plaintiffs Vifor Fresenius Medical Care Renal Pharma, Ltd. and Vifor Fresenius Medical Care Renal Pharma France S.A.S.